## REMARKS/ARGUMENTS

The specification has been revised to conform it to the preferred format for U.S. patent applications, and a Substitute Specification and Comparison Copy are submitted herewith.

Claims 53-107 are pending in this application. Claim 64 has been canceled. Claims 53, 57 and 58 have been amended. Claims 83-103 have been withdrawn. Claims 104-107 are new.

Claim 53 has been amended by combining it with now-canceled claim 64 and to remove the formal objections to it so that it now recites: "*deriving from a time interval*", which replaces the objected-to phrase: "*deriving from the time interval*".

The Office Action indicated that it seemed unclear whether the processor or another apparatus determines the time interval. Claim 53 recites in relevant parts "a processor for deriving from a time interval between said periodically recurring signal peaks a time delay ...." The language is clear and unequivocally states that it is the processor which determines the time interval.

As to claims 57 and 58, which contain narrow ranges within broader ranges, the claims have been broken up so that each recites only one range. New dependent claims 104-107 are being submitted to cover the narrower ranges that were omitted from claims 57 and 58.

In view of the foregoing, applicant requests a retraction of the Section 112 rejection.

### I. The Present Invention

The present invention improves the performance of prior art apparatus and methods such as those disclosed in WO 01/13990 or Krikorian (USPN 4,541,417) and, in particular, to provide a significant improvement in hemodynamics, i.e. the blood circulation in the body and through the heart, while enabling significant heart unloading and to reduce the electrical loading of the human body, or at least not to seriously increase it beyond the electrical loading involved in the prior art.

This is attained with an apparatus of the general kind mentioned in Krikorian. However, the present invention improves that apparatus by including a processor that is adapted to generate, in addition to an initial electrical stimulation which induces muscle contraction, a plurality of further electrical stimulation pulses with intervals between each of these further electrical stimulation pulses, so that the further electrical stimulation pulses maintain the muscle contraction over a period extending from the initial electrical stimulation substantially up to a time just before a next expected R-peak. To reduce the energy of impulses provided to the patient, the intervals between the further electrical stimulation pulses are made longer when compared to the intervals between the initial train or group of pulses; i.e. the frequency of stimulation of the further pulses is reduced compared to the frequency of the initial stimulation pulses.

Applicant recognized that less electrical energy is required to maintain a muscle contraction once it has been initiated so that the muscle contraction that is aimed at can be prolonged for the desired time by a relatively small electrical input. This recognition, first made by applicant, is an important feature of the present invention.

The present invention is further based on applicant's recognition that the heart unloading and improved circulation through the body and the heart of a person can be improved by maintaining the muscle contraction initiated generally at the predicted end of the T-wave for a period extending from the initial electrical stimulation substantially up to a time just before a next expected R-peak.

In particular the further stimulation is terminated such that the muscle contraction is ended in a time window of 85% to 95% of the preceding R-R path length, or of an average value of the preceding R-R path length after the last R-peak, as recited in amended independent claim 53. In this connection, attention is drawn to paragraph [0027] of the published application, which explains that the aim is for the muscle contraction to end between 85% and 95% of the R-R path length after the preceding R peak. To achieve this, the electrical stimulation pulses have to stop in a time window of 80% to 90% of the preceding R-R path as set forth in claim 65,

which recognizes that the electrical stimulation pulses must stop in a time window of 70% to 90% of the preceding R-R path.

## II. Non-Obviousness of the Claims

Independent claim 53 and most of the dependent claims were rejected for obviousness over Krikorian (USPN 4,541,417) in view of Karasev (USPN 5,267,623).

Applicant agrees that Krikorian discloses a sensor for detecting recurring R-R peaks of an electrocardiogram, passive components for generating a delay relative to the T-wave of a heart pulse, a trigger system, initiated by the output of either an ECG monitor or a timer 15, connected to a tetanizing trigger and a control circuit 16 which is adapted to apply a train of electrical stimulation pulses at a time related to the end of the time delay. The train of electrical stimulation pulses has a frequency and an interval between successive pulses to induce an initial muscle contraction.

Krikorian fails to teach or in any form suggest the use of a processor. Fig. 3 merely discloses a stimulation pulse generated following a T-wave. Figs. 4 to 6 of Krikorian do not disclose a processor, but merely a series of passive components interconnected to produce a delay relative to the heart rate.

Thus, Krikorian does not disclose a processor and accordingly does not disclose a processor which can be adapted to generate a plurality of further electrical stimulation pulses, or groups of electrical stimulation pulses, which have intervals that are longer than the first interval between the pulses of the first train of electrical stimulation pulses, i.e. having a reduced frequency compared to the first train of stimulation pulses.

Krikorian also fails to teach or in any form suggest that further pulses are administered to the patient to maintain the muscle contraction, or that the muscle contraction can be maintained at a reduced energy input.

Further, the apparatus of Krikorian is incapable of applying the further electrical stimulation pulses, or groups of electrical stimulation pulses, to the person over a period

extending from the first train of electrical stimulation pulses up to a time just before a next expected R-peak. Krikorian does not teach or suggest that any of the electrical stimulation pulses administered to the patient are terminated at a time such that the muscle contraction finishes in a window of 85% to 95% of the preceding R-R path length, or an average value of the preceding R-R path length after the last R-peak, as required by independent claim 53.

Thus, Krikorian does not teach the further electrical stimulation pulses, or further groups of electrical stimulation pulses, or any of their attributes, such as, for example, that these pulses are terminated in a calculated window of 70% to 90% of the preceding R-R path length (as required by claim 53), or that the further electrical pulses are administered with a frequency which is less than the stimulation frequency of the first train of stimulation pulses.

Claim 53, and most of the claims which depend from it, was nevertheless rejected for obviousness because Karasev was viewed as teaching the use of further electrical stimulation pulses that maintain muscle contraction with a reduced energy input. As a result thereof, independent claim 53 as well as the dependent claims were rejected for obviousness over Krikorian in view of Karasev.

Karasev discloses an apparatus generating electrical pulses for biological object stimulation. Karasev is directed to treating patients with disorders of a peripheral neural system with root and neurotic disfunctions, static and dynamic disorders, diseases of the ambulatory apparatus of diverse diseases of the ambulatory apparatus of diverse aetiology with disorders of the central neural system accompanied by liquor/dynamic disfunctions, cerebral blood circulation disorders and their consequences, with inflammations of the respiratory tract, diseases of the alimentary tract, vegetative neural system and other pathologic states.

Karasev does not teach using an electrotherapy apparatus capable of curing heart-related problems, far less that these are best cured in the so-called counterpulsation mode. Karasev does not disclose or in any form suggest a relationship between the length of electrical stimulation pulses and the patient's heart rate. As a result, Karasev does not even address the claimed synchronization of the pulses and the heart rate.

More specifically, Karasev discloses an apparatus which provides a first rectangular pulse of long duration and subsequent repetitive pulses of reducing amplitude. However, Karasev is silent with regard to the total duration, the amplitude or the frequency of the waveforms shown in its Figs. 1a to 1e. The pulses of Karasev are arranged into packets of a non-specified duration and with non-specified pauses between the packets. In contrast to the present invention as defined by independent claim 53, there are no intervals between the pulses of Karasev. Karasev discloses a continuous waveform in which the signal oscillates between the individual maxima and minima at a predetermined frequency. This is explained as follows:

> *"A sequence of rectangular pulses with a specified repetition rate is generated, these pulses are then duration modulated and arranged into packets of specified duration and specified pauses between packets. The duration of pulses of the specified repetition rate within a packet increases linearly to a maximal value, set in accordance with the individual sensitivity of the biological object, at which the patient experiences electric pricks of a subjectively comfortable character, then reduced linearly to zero."* (column 5, lines 28-37)

Thus, the signals shown in Figs. 1a to 1e of Karasev disclose the different shapes and frequency patterns of stimulation pulses for different biological objects, but there is absolutely no discussion of which signal form is best used for what type of biological object. Fig. 1a shows stimulating pulse 1 which is applied to the biological material for a relatively long duration. This stimulating pulse is then repeated in an adapted manner as is detailed in Figs. 1b to 1e. For this, stimulating pulse 1 is passed through an amplifier to create a waveform of stimulating pulses 2 in which, as shown in Figs. 1b to 1e, no interval is present between the individual pulses. In the present application the long interval is selected to reduce the frequency of stimulation pulses, however, Figs. 1b to 1e of Karasev all show an increase in the constant frequency of the stimulation pulses 2 relative to stimulation pulse 1.

Thus, Karasev has not recognized that a reduced frequency is beneficial to maintain muscle contraction of biological objects. Karasev also does not teach applying the stimulation pulses in correspondence to the heart rate, or that the stimulation is to be carried out in the so-called counterpulsation mode, as required by claim 53.

Since Karasev does not teach that the stimulation has to be carried out relative to the heart beat in the so-called counterpulsation mode, it cannot and does not suggest that the muscle contraction has to be maintained up until just before the end of the heart beat cycle, i.e. before the next expected R-peak, as required by claim 53. Karasev also does not suggest that the apparatus is adapted to terminate the further electrical stimulation pulses such that the muscle contraction stops in a calculated window of 85% to 95% of the preceding R-R path length, or an average value of the preceding R-R path length, after the last R-peak, as required by independent claim 53.

Neither Karasev nor Krikorian teach or suggest that the further electrical stimulation pulses, or groups of electrical stimulation pulses, can be generated at intervals longer than the first interval between the pulses of the first train of electrical stimulation pulses. Moreover, neither Karasev nor Krikorian disclose an apparatus adapted to apply the further electrical stimulation pulses or groups of electrical stimulation pulses to the person over a period extending from the first train of electrical stimulation pulses up to a time just before a next expected R-peak, as required by claim 53. In addition, as stated above, neither Karasev nor Krikorian disclose or suggest a processor adapted to terminate the further electrical stimulation pulses at a time such that muscle contraction finishes in a calculated window of 85% to 95% of the preceding R-R path length or an average value of the preceding R-R path length after the last R-peak.

In view of the foregoing, applicant submits that a person of ordinary skill in the art could not and therefore would not combine the teaching of Krikorian and Karasev and arrive at the combination recited in claim 53.

Even if a person of ordinary skill in the art were to consider an essentially arbitrary combination of Krikorian and Karasev, he could not and therefore would not arrive at the subject matter of amended independent claim 53, because both references are devoid of any disclosure concerning the above-discussed limitations of claim 53 relating to the pulse rate generation and its interaction with the person's heart rate.

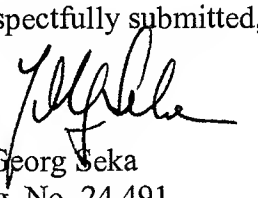
Thus, independent claim 53, as well as dependent claims 65, 67 and the remaining dependent claims, are not obvious over Krikorian in view of Karasev.

## CONCLUSION

In view of the foregoing, applicant submits that this application is in condition for allowance, and a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 273-4730 (direct dial).

Respectfully submitted,



J. Georg Seka
Reg. No. 24,491

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JGS:jhw
62765557 v1